

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.
Petitioner

v.

NOVARTIS AG
Patent Owner

Case IPR2016-_____
U.S. Patent No. 9,006,224

**DECLARATION OF MARK J. RATAIN, M.D. IN SUPPORT OF PETITION
FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,006,224**

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I, Mark J. Ratain, M.D., resident of Chicago, Illinois, hereby declare as follows:

I. INTRODUCTION AND QUALIFICATIONS

1. I have been retained by Par Pharmaceutical, Inc. (“Par”) to provide my opinion concerning the validity of U.S. Patent No. 9,006,224 (Exhibit 1001; “the ’224 patent”) in support of Par’s Petition for *Inter Partes* Review of the ’224 patent (“’224 Petition”).

2. I graduated from Harvard University *magna cum laude* in 1976 with an A.B. in Biochemical Sciences. I obtained my M.D. from Yale University School of Medicine in 1980. I completed my internship and residency at the Johns Hopkins Hospital in Baltimore, MD from 1980-1983. I completed a fellowship in Hematology/Oncology at the Department of Medicine at the University of Chicago from 1986-1988.

3. In 1986, I joined the Department of Medicine, Section of Hematology/Oncology and Committee on Clinical Pharmacology at the University of Chicago as an Instructor and become a Professor in that department in 1995. In 2002, I became the Leon O. Jacobson Professor in the Department of Medicine, Section of Hematology/Oncology and Committee on Clinical Pharmacology and Pharmacogenomics, and Comprehensive Cancer Center at the University of Chicago.

4. In 1991, I became the Director of the Developmental Therapeutics Program at the Cancer Research Center at the University of Chicago. In 1992, I became Chairman of the Committee on Clinical Pharmacology and Pharmacogenomics at the University of Chicago. In 1995, I became Co-Director of the Clinical and Experimental Therapeutics Program of the Cancer Research Center at the University of Chicago. In 1999, I became the Associate Director for Clinical Sciences at the Comprehensive Cancer Center at the University of Chicago. In 2010, I became the founding Director of the Center for Personalized Therapeutics and Chief Hospital Pharmacologist at the University of Chicago.

5. I have received numerous honors and awards over my career. These include election to the Association of American Physicians in 2007, and awards from multiple institutions (MD Anderson Cancer Center, University of North Carolina, University of Nebraska, University of Utah), foundations (Pharmaceutical Research and Manufacturer's Association of America Foundation) and professional societies (American Association of Pharmaceutical Scientists, American Society for Clinical Pharmacology and Therapeutics, American Society of Clinical Oncology, American College of Clinical Pharmacology).

6. I have also had extensive involvement with the American Society of Clinical Oncology (ASCO), dating back to 1990 when I was appointed Chair of ASCO's Audit and Finance Committee. I was subsequently elected to the position

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